DEC 18 2013

Medacta International

510(k) Summary

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Contact Person: Mr. Adam Gross
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Date Prepared: September 9, 2013

DEVICE INFORMATION

Trade/Proprietary Name: M.U.S.T. Extension
Common Name: Pedicle screw spinal system
Classification Name: orthosis, Spinal pedicle fixation, for degenerative disc disease

21 CFR 888.3070, 21 CFR 888.3060, 21 CFR 888.3050
Class III
Device Product Codes: MNI, MNH, NKB, KWQ, KWP

Predicate Devices:

510(k)	Product	510(k) Holder	Clearance Date
K121115	M.U.S.T Pedicle Screw System	Medacta International	7/18/2012
K083393	XIA3	Stryker	4/23/2009
K042962, K091445	CD Horizon	Medtronic	12/14/2004, 9/27/2010
K072022	Valeo Pedicle Screw System	Amedica	11/19/2007
K041119	Expedium	Depuy	7/19/2004

Product Description

The M.U.S.T. Extension consists of the following implants that are to be used as part of the M.U.S.T. pedicle screw system (K121115):

- New sizes (diameter and length) of the solid polyaxial pedicle screws that were cleared under K121115
- Solid and cannulated monoaxial pedicle screws
- Cross connectors

The M.U.S.T. Extension is intended to be used as part of the M.U.S.T. pedicle screw system for the stabilization and the fusion of the lumbar and thoracic spine. The M.U.S.T. Extension includes different sizes of screws and cross connectors. The screws are fixed in the pedicle and the vertebrae. The straight and pre-bent rods (K121115) act as a connector between the different screws to create a stable construct. The cross connectors act as a stabilizing construct between the rods on each side of the vertebrae. The cross connectors have an adjustable medial/lateral length in order to address various distances between the rods depending on the patient's anatomy. Rod distances from 35mm to 98 mm can be addressed with the various connector sizes. The connector offers an angular adjustable central joint in order to align the connection to the rod. The angular adjustable feature as well as the size range of the connectors is within the range of the predicate devices. The M.U.S.T. Extension can be applied with the common surgical technique for posterior instrumentation.

The M.U.S.T. Extension cross connectors are made of Titanium alloy (Ti6Al4V ELI - ISO 5832-3, ASTM F136) and come in 4 sizes: 35-42, 40-50, 48-66, and 64-98. The M.U.S.T. Extension pedicle screws are made of either Titanium alloy (Ti6Al4V ELI - ISO 5832-3, ASTM F136) or a combination of Titanium alloy (Ti6Al4V ELI - ISO 5832-3, ASTM F136) and CoCrMo (ISO 5832-12, ASTM F 1537). The M.U.S.T. Extension solid polyaxial pedicle screws have diameters of 8, 9, and 10mm and lengths between 20 and 100mm in 5mm increments. The M.U.S.T. Extension solid monoaxial pedicle screws have diameters between 4.5 and 7mm and lengths between 25 and 65mm in 5mm increments in addition to screws with a diameter of 8mm with lengths between 25 and 90mm. The M.U.S.T. Extension cannulated monoaxial pedicle screws have diameters between 5 and 7mm and lengths between 40 and 60mm in 5mm increments. The screw shaft is color anodized to simplify the identification of the screw diameter. The pedicle screw has a dual lead thread to simplify the screw insertion and reduce the number of turns. The threads are designed with a cylindrical diameter. The construct is secured using a set screw made of CoCrMo (ISO 5832-12, ASTM F 1537). The pedicle screws are available both in sterile and unsterile packaging while the cross connectors are available in sterile packaging.

Indications for Use

The M.U.S.T. pedicle screw system is intended for posterior non-cervical pedicle fixation (T1-S2/ilium) or anterolateral fixation (T8-L5). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Comparison to Predicate Devices

The indications for use and materials of the M.U.S.T. Extension are identical to the previously cleared predicate devices. The design features, geometries, and sizes of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the M.U.S.T. Extension are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

The modification to the device system to include the addition of M.U.S.T. Extension was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system. The testing was conducted on the worst case component size and option/design based on engineering analysis. The M.U.S.T. Extension was compared to the worst case of the predicate devices and it was determined that the M.U.S.T. Extension are not worst case.

M.U.S.T. Extension has similar performance testing as the predicates in terms of:
Static compression/bending yield strength ASTM F 1717
Fatigue compression/bending strength ASTM F 1717
Static compression/bending stiffness ASTM F 1717
Static torsion yield strength ASTM F 1717
Static torsion stiffness ASTM F 1717

Conclusion:
Based on the above information, the M.U.S.T. Extension can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2013

Medacta International SA
% Medacta USA
Mr. Adam Gross
4725 Calle Quetzal, Unit B
Camarillo, California 93012

Re: K132878
Trade/Device Name: M.U.S.T. Extension
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: September 27, 2013
Received: September 30, 2013

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132878

Device Name: M.U.S.T. Extension

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Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Zane W. Wyatt -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132878